

# Patients with Type 2 DM and Hypertension

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## Abstract

Patients that have type 2 diabetes mellitus have a great risk of having several comorbidities. These include hypertension, coronary artery disease, stroke, obesity, hyperlipidemia, chronic kidney disease and neuropathy, along with many others. On average 1 in 5 Americans or 22.5% has heart disease. According to the American Heart Association, that is expected to rise to 45.1% by 2035. According to the CDC, 30.3 million Americans have diabetes. Only 23.1 million of those have been diagnosed and are being treated. An estimate 33.9% of Americans 18 years and older have prediabetes.

## Introduction

### Proposal

**Patients with type 2 DM and hypertension: Cardiovascular risk:** Diabetes Mellitus is prevalent condition in the United States that keep growing. An estimated 30.3 million Americans have diabetes mellitus. These patients are at a much higher risk for comorbidities. The following risk factors increase the risk for complications: smoking, overweight and obesity, physical inactivity, hypertension, hyperlipidemia, and having an A1C of over 9%. In 2014, an estimated 7.2 million hospitalizations occurred for diabetic patients aged 18 years and older. 105,604 patients were hospitalized for cardiovascular disease that also have a diagnoses of diabetes mellitus (Centers for Disease Control and Prevention, 2017).

## Specific Aims

This study will emphasize the importance of blood pressure control in patients in order to reduce the risks of cardiovascular death, myocardial infarctions and strokes. Patients with type 2 diabetes mellitus that already have hypertension are at a much greater risk of developing cardiovascular complications. There is limited literature specifically regarding patients with type 2 diabetes and hypertension. The aim of this study is to combine the available information and gather new information if needed to determine an optimal blood pressure goal for patients with Type 2 DM.

The Advance Trial was conducted by the ADVANCE Collaborative group in order to determine the effects of intensive glucose control over standard glucose control along with routine blood pressure lowering strategies for both groups. The trial consisted of 11,140 patients. 5,571 were assigned to the intensive glucose control group. 5,569 were assigned to the standard glucose control group. The aim of this study was to determine if targeting an A1C of less than 6.5% would be more beneficial in reducing the risks of microvascular and macrovascular complications. The study also considered whether standard blood pressure lowering provisions added reduced risk of microvascular and macrovascular complications. In order to meet criteria, patients had to be older than 55 years of age and have an additional risk factor

for vascular complications. The patients in the intensive group were not only given gliclazide but were encouraged to lose weight and exercise, add other agents to the gliclazide as necessary, and add insulin therapy as needed. The standard control group were treated according to local practice. The outcomes were assessed and recorded at follow up appointments every 6 months with the exception of retinopathy, albumin to creatinine ratio, mini mental scores and quality of life. Those were recorded at 2 years, 4 years and the end of the study. At the end of the study, 18.1% of the intensive control group presented with major macrovascular or microvascular events, while 20.0% of the standard control group presented with these events. There were 1,031 deaths during the trials but there were no significant differences in the amount that came from each trial group. Systolic blood pressure was greatly lowered in the individuals of the intensive control group. This study demonstrated the fact that it is possible to achieve stringent levels of glycemic control with conventional agents [1].

### Blood pressure targets in type 2 diabetes

**An aggressive approach:** In the article "Blood Pressure Targets in Type 2 Diabetes: Evidence against or in Favor of an Aggressive Approach" by Giuseppe Mancia and Guido Grassi, the authors considered the optimal goal blood pressure in order to decrease the risk of cardiovascular and renal events in patients with type 2 diabetes mellitus. They gathered their evidence from randomized trials, trial meta-analyses, and large observational studies. These included: Appropriate Blood Pressure Control in Diabetes (ABCD), Action to Control Cardiovascular Risk in Diabetes (ACCORD), Action in Diabetes and Vascular Disease (ADVANCE), and the UK Prospective Diabetes Study (UKPDS). Mancia and Grassi compared and contrasted the studies to determine an optimal blood pressure goal for patients. At this point in time, guidelines are not clear and concise. Certain organizations recommend 130/80 mmHg, while others recommend 140/90 mmHg. Lowering to less than 120 mmHg is not recommended as it may cause more harm than benefit. The synthesis of randomized control trials, observational studies and trial meta-analyses concludes that a systolic blood pressure reduction to 130-139 mmHg effectively reduces the risk of cardiovascular and renal complications. It is important to stress that blood pressure goals should vary from patient to patient on a case by case basis. Practitioners should also be aware that controlling blood pressure in diabetic patients may prove to be much more difficult than in normotensive patients [2].

**HOT randomized trial:** In the article "Effects of Intensive Blood-Pressure Lowering and Low-Dose Aspirin in Patients with Hypertension: Principal Results of the Hypertension Optimal Treatment Randomized Trial" by Hansson, Zanchetti, Carruthers, Dahlof, Elmfeldt, Julius, Menard, Rahn, Wedel, and Westerling, 18,790 patients ages 50-80 years old were randomly assigned a target diastolic blood pressure target. 6,264 were allocated to the less than 90 mmHg group, 6,292 were allocated to the less than 85 mmHg group and 6,262 were assigned to the less than 80mmHg group. Felodipine was the baseline agent given and then other agents were added according to a 5-step regimen. 9,399 were also randomly assigned aspirin while the rest were given a placebo. Results concluded that the lowest incidence of cardiovascular

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events occurred at 82 mmHg while the lower risk of cardiovascular mortality occurred at 86 mmHg. In patients with diabetes, a 51% reduction of major cardiovascular events occurred in the target group of less than 80 mmHg. Aspirin reduced the risk of myocardial infarction by 36% but had no effect on the reduction of stroke. In conclusion, a reduction of diastolic blood pressure to 82 mmHg was deemed safe and effective in reducing the risk of cardiovascular events [3].

**The systolic blood pressure intervention trial:** In the article "The Design and Rationale of a Multicenter Clinical Trial Comparing Two Strategies for Control of Systolic Blood Pressure: The Systolic Blood Pressure Intervention Trial" by Ambrosius, Sink, Foy, Berlowitz, Cheung, Cushman, Fine, Goff, Johnson, Kileen, Lewis, Oparil, Reboussin, Rocco, Snyder, Williamson, Wright, and Whelton, a multicenter, randomized control trial compared the reduction of systolic blood pressure to either less than 140 mmHg or to less than 120 mmHg. Participants were required to be over the age of 50 with an average baseline blood pressure of greater than 130 mmHg and must have indication of cardiovascular disease, chronic kidney disease, or 10-year Framingham Score of greater than 15%. Outcomes measured included: myocardial infarction, acute coronary syndrome, stroke, heart failure, cardiovascular disease, death, decline in kidney function, dementia, decline in cognitive function and small vessel cerebral ischemic disease. The trial took place between November 2010 and March 2013. 9,361 patients were included in the trial. 4,678 were included in the group that was required to lower their systolic blood pressure to less than 120 mmHg. 4,683 were required to lower their blood pressure to under 140 mmHg. The ACCORD model was used as a basis for this trial. The primary conclusion is that myocardial infarction (MI), acute coronary syndrome (ACS), stroke, congestive heart failure (CHF), or cardiovascular (CV) death, were substantially lowered in the intensive BP management group compared with the standard management group. This trial showed such promising results that it was ended at the 3-year mark instead of going the full 5 years [4].

**Longitudinal patterns:** "Longitudinal Patterns of Blood Pressure, Incident Cardiovascular Events and All-Cause Mortality in Normotensive Diabetic People" by Wu, Jin, Vaidya, Jin, Huang, Wu and Gao address the huge financial impact that diabetes has on health care and social economy. This study includes 3,159 diabetic participants free of hypertension, cardiovascular disease and cancer. 831 of these participants had a blood pressure below 120/80. 2,328 of the participants had baseline blood pressures between 120 and 139/80 and 89 mmHg. The participants were followed for 7 years. During that 7 years, there were 247 deaths and 177 cardiovascular events. It was determined during this study that patients that have a rise or drop of 10-20 points in blood pressure are at increased risk for cardiovascular events [5].

**Tight blood pressure control in type 2 diabetes:** "The Evidence Base for Tight Blood Pressure Control in the Management of Type 2 Diabetes Mellitus" by Snow, Weiss, and Mottur-Pilson weighs the reduction of macrovascular complications with tighter blood pressure restrictions on patients with type 2 diabetes. In this systematic review, 3 randomized control trials were compared. These trials included: Systolic Hypertension in the Elderly Program (SHEP), the Hypertension Detection and Follow-up Program (HDFP) and the Systolic Hypertension in Europe (Syst-Eur). The SHEP results stated that a reduction of 9.8 mmHg in systolic pressure reduced total cardiac events significantly. In the HDFP, participants were assigned to intensive care and usual care. In an analysis by the Cochrane group of the HDFP, it was determined that the intensive group had a drastically lower chance of cardiovascular mortality and morbidity. In the Syst-Eur, participants were assigned a placebo or nitrendipine. The average systolic reduction was 8.6 mmHg in the group with nitrendipine and 3.9 mmHg in the placebo group. This resulted in a 62% reduction in all cardiovascular events. It was determined that blood pressure control must be of the utmost importance in patients with hypertension and type 2 diabetes mellitus [6].

**Newly diagnosed type 2 diabetics and blood pressure:** "Association of Systolic and Diastolic Blood Pressure and all-Cause Mortality in People with Newly Diagnosed Type 2 Diabetes: Retrospective Cohort Study" by Vamos, Harris, Millett, Pape, Khunti, Curcin, and Molokhia highlights the effects of systolic and diastolic blood pressure in patients with newly diagnosed type 2 diabetes, both with and without evidence of cardiovascular disease. The

study included 126,092 adult patients that were newly diagnosed with type 2 diabetes. 12,379 participants had a previous stroke or myocardial infarction before the study began. At a 3.5 year follow up, 25,495 of the participants had passed away. In patients with previous cardiovascular disease, tight blood pressure control (under 130/90) did not show improved survival rates. Blood pressure under 110/75 mmHg was associated with increased risks for cardiovascular disease [7].

**Goals, agents and priorities:** Vijan and Hayward stated that "hypertension in patients with type 2 diabetes mellitus is a prevalent condition that leads to substantial morbidity and mortality." In the article "Treatment of Hypertension in Type 2 Diabetes Mellitus: Blood Pressure Goals, Choice of Agents and Setting Priorities in Diabetes Care," goals and optimal treatment for patients with hypertension and type 2 diabetes was evaluated. Randomized control trials that assessed the pharmacologic treatment of hypertension in diabetic patients were used. These studies included the macrovascular and microvascular outcomes. Studies were discovered by utilizing the Cochrane Library, MEDLINE, meta-analyses and expert recommendation. It has been proven that treatment of hypertension in type 2 diabetes is of great benefit. Targets of systolic blood pressure less than 135 mmHg seem to be optimal. While thiazide diuretics, angiotensin-converting enzyme inhibitors and angiotensin-II blockers are first line treatment for hypertension in diabetics, studies that evaluate the different classes have not suggested which agents are superior. Treatment goals of less than 135/80 mmHg produces drastic benefits. Lowering blood pressure to the optimal goals may prevent many macrovascular and microvascular events. The article states that controlling blood pressure in diabetic patients proves to be just as important as controlling blood glucose levels [8].

**Control of blood pressure and cardiovascular outcomes:** In a review article by Vargas-Uricoechea and Caceres-Acosta, the effects of blood pressure control and cardiovascular outcomes in type 2 diabetic patients. This study was conducted due to the fact that the information regarding blood pressure and cardiovascular effects are limited. Due to the comorbidities that coincide with diabetes mellitus, information on patients strictly with diabetes is limited. In the past, recommended blood pressure goals have ranged from 130/80-140/90 mmHg. In this review, the authors evaluated several randomized control trials including SHEP, Syst-Eur, UKPDS, HOT, ABCD, HOPE, IDNT, PROGRESS, ALLHAT, ADVANCE, STENO-2, ONTARGET, SANDS, ACCOMPLISH, INVEST, ACCORD, Secondary Prevention of Small Subcortical Strokes and VALUE. It was determined that there is no clear standard on an optimal level of blood pressure in diabetics and that levels should be determined on a case by case basis. It was also determined that patients with diabetes should not have a blood pressure below 130/90 mmHg due to increased risks of cardiovascular complications except in the case of patient that have a high risk of cerebrovascular events, such as patients with a history of stroke, neuropathy and proteinuria. In patients with a high risk of cerebrovascular events, blood pressure should be maintained under 130/80 mmHg [9].

**Intensive blood pressure lowering in type 2 diabetics:** Wang, Chen, Xu, Lu, Cao, and Yu performed a meta-analysis on several randomized control trials to determine if intensive blood pressure control reduced the risks of all-cause mortality in type 2 diabetic patients. They searched PUBMED, EMBASE, Science Citation Index and Cochrane Library to find 16 studies that met the inclusion criteria. According to the data found in this analysis, intensive blood pressure lowering proves to be more beneficial than a standard blood pressure lowering approach from a cardiovascular standpoint. Further studies were recommended to more clearly evaluate the harms and benefits of blood pressure targets lower than those already recommended. It was determined that patients should focus on keeping their blood pressure in the optimal range of 130-140/80-90 mmHg. Intensive blood pressure lowering resulted in substantial reductions in all-cause mortality, cardiovascular events, stroke, myocardial infarction, and albuminuria progression. It did not prove to be beneficial in lowering risks of end stage kidney disease, heart failure or non-cardiovascular deaths.

**Blood pressure targets for hypertension in people with diabetes mellitus:** Arguedas, Leiva, and Wright conducted a literature review in order to

ascertain whether lower blood pressure targets are associated with reduction in mortality and morbidity in comparison with standard blood pressure targets in diabetic patients. Blood pressure targets of less than 130/85 and 160/90 were compared in order to determine if they reduced mortality and morbidity. Arguedas, Leiva, and Wright searched the Database of Abstract Reviews of Effectiveness, Hypertension Group Specialized Register, Cochrane Register of Controlled trials, MEDLINE, EMBASE and ClinicalTrials.gov, and the Cochrane Database for reviews that met their criteria. The authors separately reviewed the randomized control trials and evaluated the primary outcomes of total serious adverse events, renal disease, congestive heart failure, myocardial infarction, and total mortality. At the time of the review, there was not enough evidence to support lowering blood pressure below the standard targets in patients with hypertension and diabetes. More trials are needed to determine total mortality and morbidity. The authors concluded that the optimal blood pressure goal is 140/90 mmHg [10].

## Systematic review

**Lowering blood pressure in type 2 patients:** Toklu and Bangalore produced a systematic review of 45 randomized control trials. Among the trials there were a total of 104,856 participants with type 2 diabetes mellitus whom did not have set blood pressure targets. In the review, they compared different antihypertensive agents with placebos. They assessed both macrovascular and microvascular complications such as: all-cause mortality, cardiovascular disease, heart disease, stroke, retinopathy and albuminuria. The conclusion was made that a reduction of systolic blood pressure to less than 140 mmHg was beneficial but lowering to below 130 mmHg did not provide any additional benefits except for a small reduction in stroke risk and albuminuria. It was also determined that blood pressure goals should be implemented on a case by case basis [11].

## Methods

A systematic review and meta-analysis will be conducted using the methodology recommended by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for meta-analyses of interventional studies. 12 Relevant studies will be selected using the following search terms: anti-hypertensive agents or hypertension or diuretics, thiazide or angiotensin-converting enzyme or receptors, angiotensin/antagonists & inhibitors or tetrazoles or calcium channel blockers or vasodilator agents or the names of all BP-lowering drugs listed in the United States Pharmacopeia and the National formulary as keywords or text words or the MeSH (Medical Subject Headings [of the US National Library of Medicine]) term blood pressure/drug effects. The current strategy used to identify BP-lowering trials published on MEDLINE, from January 1, 1966, to October 28, 2014, restricted to those published in MEDLINE-defined core clinical journals will be utilized. The preliminary exploration will be conducted by an experienced research librarian and no language restrictions will be applied. Studies will be limited to clinical trials, controlled clinical trials, randomized controlled trials, or meta-analyses. Bibliographies of included studies and bibliographies of identified meta-analyses will be researched by hand. Each trial will be manually examined for patients with diabetes and searched for any reporting of results for the diabetic subgroup.

## Eligibility

Randomized controlled trials of BP-lowering treatment in which the entire trial population comprised patients with diabetes or in which the results of a diabetic subgroup were able to be obtained will be included in the systematic review. Randomized trials published between January 1966 and July 2019 will be incorporated. No trial will be rejected due to the existence of comorbidities at baseline. Trials conducted in type 2 diabetic patients with heart failure and after myocardial infarction will be included. Trials that were conducted in patients predominantly with type 1 diabetes were excluded. For inclusion, all trials will be expected to have more than 1000 patient-years of follow-up in each randomized group to minimize risk of bias associated with small trials [12-14].

## Conclusion

According to a position statement by the American Diabetes Association in 2017, hypertension puts patients at a strong risk for atherosclerotic cardiovascular disease (ASCVD), which is the leading factor in direct and indirect costs among diabetic patients. ASCVD includes acute coronary syndrome, stroke, myocardial infarction, transient ischemic attacks, peripheral arterial disease, angina, and coronary or arterial revascularization. The ADA recommends that patients have their blood pressure checked in both arms at every visit. Patients with hypertension should have a blood pressure monitoring system at home. ADA recommends a blood pressure target of 140/90 mmHg unless the patient is at a high risk for cardiovascular events. All comorbidities must be considered when deciding on an optimal goal. Patients should not only be encouraged to take their medications as prescribed but to change their lifestyle to help lower their blood pressure. Patients should be encouraged to lose weight if overweight or obese, lower sodium intake, increase potassium intake, increase fruit and vegetable consumption, decrease alcohol intake if applicable and increase physical activity. Hypertension can have grave effects on all patients but those with type 2 diabetes are at a greater risk for microvascular and macrovascular complications.

## Conflict of Interest

None.

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